

REMARKS

Claims 1-6 and 9-11 remain in the application. Only Claim 1 is in independent form.

Claim 9 stands rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, it is stated in the Office Action that it is "not known which disorder or condition can be effected or facilitated by activating ORL1-receptor and which disorder or condition is not. One skilled in the art cannot say for sure whether a given disorder or condition can be effected or facilitated by activating ORL1-receptor or not."

Applicants respectfully submit that Claim 9, as written, is not indefinite since one of ordinary skill in the pharmaceutical arts, particularly one well versed in the opioid therapeutic field, would understand quite well the diseases, disorders or conditions "which can be effected or facilitated by activating ORL1-receptor". As stated in our previous amendment, a number of disorders and conditions are set forth in the specification to support this language at pages 4-6. In order to further support the state of the art which existed at the time the present application was filed, Applicants submit herewith a copy of a Journal of Medicinal Chemistry article entitled, Discovery of the First Potent and Selective Small Molecule Opioid Receptor-like (ORL1) Antagonist: 1-[(3R,4R)-1-Cyclooctylmethyl-3-hydroxymethyl-4-piperidyl]-3-ethyl-1,3-dihydro-2H-benzimidazol-2-one (J-113397) from Volume 42, Number 25, pages 5061-5063 (December 16, 1999). Referring specifically to the second paragraph on page 5061, numerous conditions and/or disorders associated with ORL1 are discussed. Specifically, the article states that ORL1 "may have important roles in the regulation of pain response,⁴ morphine tolerance,⁵ learning and memory,⁶ food intake,⁷ anxiety,⁸ the cardiovascular system,⁹ locomotor activity,¹⁰ and so on.¹¹" Applicants respectfully submit that the present specification sufficiently sets forth the diseases, disorders or conditions "which can be effected or facilitated by activating ORL1-receptor". Applicants further submit that the attached article provides additional support for the same contention.

Accordingly, in view of the comments set forth above, Applicants request withdrawal of this rejection under 35 U.S.C. §112, second paragraph.

Claims 9 and 10 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, while enabling a method of treating pain, allegedly does not reasonably provide

enablement for the treatment of all other indication recited in the claims. The Examiner cites to the examples of "Alzheimer's Disease, tolerance to narcotic analgesics, dependence on narcotic analgesics, Parkinson's Disease, etc." Further, the Examiner urges that there are no known compounds of similar structure to those of the present invention "which have been demonstrated to treat" these diseases.

Applicants respectfully submit that the Examiner has presented no sufficient reason to doubt the objective truth of these statements that compounds, which modulate ORL1-receptors, are useful in the treatment of diseases, disorders or conditions referred to in the claims. Applicants again refer the Examiner to the arguments made in their previous amendment and response with regard to this rejection. Additionally, Applicants wish to again refer the Examiner's attention to the Journal of Medicinal Chemistry article discussed above and submitted herewith. In that article, a compound of similar structure to those claimed in the present application is described as being able to bind to ORL1. As stated above, it has been noted that ORL1 may have important roles in the regulation of various conditions as set forth above. Accordingly, Applicants respectfully submit that the publication provides further support for the treatment of a disorder or condition which can be effected or facilitated by activating ORL1-receptor. Accordingly, Applicants respectfully request reconsideration withdrawal of the rejection of Claims 9 and 10 under 35 U.S.C. §112, first paragraph.

Claims 1-6 and 9-11 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ito et al. (US 6,172,067). Applicants respectfully submit that even though US 6,172,067 has an earlier filing date in the United States than the present application, it was granted after the filing date of the present application and thus falls under 35 U.S.C. §102(e) and, therefore, since both US 6,172,067 and the present application are owned by the same assignee, US 6,172,067 cannot be used under 35 U.S.C. §103(c) for the purpose of establishing obviousness. Accordingly, Applicants request withdrawal of the rejection under 35 U.S.C. §103(a).

Claims 1-6 and 9-11 stand rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over Claims 1-9 of United States Patent Number 6,172,067. Applicants respectfully submit that since, as stated immediately above, US Patent Number 6,172,067 cannot be utilized as prior art against the presently pending application, that only the claims thereof can be utilized in order to formulate a rejection under

the judicially created doctrine of obviousness-type double patenting. It is respectfully submitted that the claims of US Patent Number 6,172,067 do not provide any suggestion or motivation that would lead on of ordinary skill in the art to choose the specific invention claimed herein. In the absence of a specific motivation in the art itself to give one of ordinary skill a reasonable expectation of success, there can be no assertion of obviousness.

Accordingly, Applicants respectfully submit there is no basis for asserting the obviousness of the particular compounds of the present invention and Applicants request withdrawal of this rejection. Upon the allowance of claims for the present application, Applicants would reconsider the filing of a terminal disclaimer to obviate the pending rejection.

In view of the foregoing remarks, Applicants respectfully submit that the application is in condition for allowance, which allowance is respectfully solicited.

The Commissioner is authorized to charge any fee or credit any over payment in connection with this communication to our Deposit Account No. 23-0455.

Respectfully submitted,

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Attachment: Journal of Medicinal Chemistry Article

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